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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,719	03/23/2004	Kenneth P. Hoyme	279.721US1	2654

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/806,719

Applicant(s)

HOYME ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-24,26-32 and 51-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,7,10-24,27-30,32 and 51-56 is/are rejected.
- 7) ☒ Claim(s) 4,5,8,9,26 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/8/2006 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 6, 7, 11, 18-22, 24, 25, 29, 30, 51, 53, and 55 rejected under 35 U.S.C. 102(b) as being anticipated by Shahandeh (US 6,532,389, hereinafter "Shahandeh").

4. In regards to claims 1, 2, 24, 25, 51 and 53, Shahandeh discloses an IMD comprising memory (94) and a controller circuit (60) wherein the controller enters a memory scrubbing mode (316 and 320) with an increased rate of error checking when the controller determines the IMD is in a high-energy radiation environment (Fig. 7).

Examiner is interpreting Shahandeh's "controller determine[ing] the implantable device is in a high-energy radiation environment" as being performed by the same method as claimed in claim 2 (i.e. detecting a rate of memory errors exceeding a threshold at Fig. 7's step of "Page Parity Error Detected?" The rate of errors is 1 per page.). The "increased rate of error detection" is disclosed in the steps following element 314 in Figure 7 (i.e. by checking column and array parity bits). In other words, the controller determines that the device is in a high-energy radiation environment (col. 1, line 61; errors are caused by "high-energy radiation" environments) by detecting that a rate of memory errors exceeds a programmable threshold error rate (i.e. at a rate of 1 per page), wherein the memory scrubbing mode has an increased rate of error checking (i.e. at a higher rate of the number of columns per page).

5. In regards to claims 6 and 29, the controller circuit exits the memory scrubbing mode when the IMD is no longer in the radiation environment (Fig. 7, "NO" at "Page Parity Error Detected?").

6. In regards to claims 7 and 30, the determination is made by detecting a rate that is less than a threshold (zero per page).

7. In regards to claim 11, the controller detects and corrects single bit errors (316 and 320).

8. In regards to claim 18, the IMD includes an output and therapy circuit (40-58, 70 and 78).

9. In regards to claims 19 and 20, the memory scrubbing mode is performed at a lower priority than the therapy (col. 14, line 22). The memory scrubbing is performed between therapies.
10. In regards to claims 21 and 55, the IMD further comprises an electrical input and output to provide therapy to the heart (Figs. 1 and 2).
11. In regards to claim 22, the IMD includes a cardioverter defibrillator (116).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
14. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahandeh. Shahandeh discloses the essential features of the claimed invention,

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including detecting multiple bit errors (abstract), but does not disclose correcting multiple bit errors. However Shahandeh teaches that it is well known in the art (col. 2, line 28) to correct multiple bit errors to avoid corruption of large amounts of memory. Therefore, it would have been obvious to modify Shahandeh's invention by correcting multiple bit errors to avoid corruption of large amounts of memory.

15. Claims 3, 10, 13, 14, 16, 17, 26-28, 32, 52, 54 and 56 rejected under 35 U.S.C. 103(a) as being unpatentable over Shahandeh in view of Foster et al. (US 2003/0036776, hereinafter "Foster"). Shahandeh discloses the essential features of the claimed invention except for utilizing a sensor to determine a high energy radiation environment exceeding background radiation, exiting the high-radiation mode after a predetermined period of time, or enabling and disabling the high-radiation mode via an RF transmitter associated with the source. Foster teaches of utilizing a sensor to determine a high energy radiation environment exceeding background radiation (par. 0041) to protect the most sensitive components of the device, exiting the high-radiation mode after a predetermined period of time (par. 0045) to only utilize the protective mode during at-risk periods, or enabling and disabling the high-radiation mode via an RF transmitter associated with the source (par. 0053) to accurately change modes only during application of radiation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shahandeh's invention by utilizing a sensor to determine a high energy radiation environment exceeding background radiation to protect the most sensitive components of the device, exiting the high-radiation mode after a predetermined period of time to only utilize the

protective mode during at-risk periods, or enabling and disabling the high-radiation mode via an RF transmitter associated with the source to accurately change modes only during application of radiation.

16. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahandeh in view of Foster et al. as applied to claim 13 above, and further in view of Linberg (US 2002/0032470, hereinafter "Linberg"). The modified invention of Shahandeh includes the essential features of the claimed invention except for programmer connectivity to a global computer network. Linberg teaches of an implantable cardiac rhythm management device whose programmer communicates with a web-based data center to import expertise to the patient environment (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the modified invention of Shahandeh with a programmer with connectivity to a global computer network to allow a remote medical expert to diagnose problems, monitor the patient, or provide software enhancements to the implanted device.

17. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahandeh in view of Ullestad et al. (US 6,635,048, hereinafter "Ullestad"). The modified invention of Shahandeh includes the essential features of the claimed invention except for providing drug therapy to the patient. Ullestad teaches of providing a drug delivery device with a back-up memory to provide a reliable device to treat a variety of diseases that require controlled release drugs. Therefore, it would have been obvious to provide the modified invention of Shahandeh with a drug delivery device to

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provide a reliable means to treat a variety of diseases that require controlled release drugs.

Allowable Subject Matter

18. Claims 4, 5, 8, 9, 26, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

19. Applicant's arguments filed 5/17/2006 have been fully considered but they are not persuasive. Applicant argued that Shahandeh does not disclose determining that a device is in a high-energy radiation environment by detecting that a rate of memory errors exceeds a programmable threshold rate, but only checking a page whenever a page parity error is detected. However, Shahandeh discloses that a "high-energy radiation environment" is one wherein memory errors occur (col. 1, line 61). Therefore, Shahandeh's detection of a memory error is also a detection of a "high-energy radiation environment". Further, as indicated above, Shahandeh discloses that if this determination is made (i.e. there exists an error for a certain page of data, per examination of the parity bit), the rate of error checking is increased (i.e. all columns of the certain page are checked). In this case, "rate" is being interpreted as the number of "checks" per page of data.

20. Applicant further argued that the rejection under 35 USC 103(a) of claim 12 is improper because Shahandeh's disclosed system does not actually correct multiple bit errors, but merely discloses an "ideal" system with difficulties yet to be addressed. However, Shahandeh discloses that: "By providing five error detection and correction bits per byte, single or multiple-bit errors can be detected and corrected using hardware as the data is read (col. 2, line 39)"; and later describes how such a system is less than optimal in practice because, "[the] overhead necessitated by such a system is 62.5% (col. 2, line 43)". It has been held that the mere showing of less than optimal performance does not vitiate the fact that something has been disclosed (MPEP 2123). As Shahandeh teaches that it is desirable to provide an error-checking algorithm with multiple-bit error checking, rejection under 35 USC 103(a) is proper and stands, regardless of the "less than optimal" performance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK**


7/10/06


GEORGE R. EVANISKO
PRIMARY EXAMINER

7/13/6